Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002, OMB 0851-0031*
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons of Paperwork in a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

	Complete if Known		
Application Number	09/757,688		
Filing Date	January 11, 2001	•	
First Named Inventor	Wolfgang HEIL et al.		
Group Art Unit	1615		
Examiner Name	L.S. Channavajjala		
Attorney Docket Number	PLOVIN-2A		

				U.S. PATENT DOCUM	MENTS	
		U.S. Patent Docum	nent		Date of Publication of	Pages Columns I loss Whom Paleurant
Examiner tritials	No.' Nur	Number Kind Co		Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
- 5		5,858,405		Gast	1/12/1999	**************************************
A		5,897,539		Elliesen et al.	4/27/1999	
-		 				
		 			· · · · · · · · · · · · · · · · · · ·	
		<u> </u>				
	-	 			· · · · -	
-						
		 				
 		 	 -			
•						
	<u> </u>	11				

				FOREIG	N PATENT DOCU	IMENTS		
	Cita	Foreign Patent Document			Name of Patentee	Date of Publication of	Pages, Columns, Lines,	
	Cite No. ¹	Office ³	Number ⁴	Kind Code ⁵ (<i>if known</i>)	or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T _o
		ļ						
					· · · · · · · · · · · · · · · · · · ·			
		·	<u> </u>					
		<u></u>						
	ļ	ļ	ļ					
<u> </u>						<u> </u>		

Examiner Signature	L. Chan	ravagales	Date Considered	4/14/06	
					نسسسين وسيد

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WiPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WiPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark the if English language Translation is attached.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031 ent and Trademark Office: U.S. DEPARTMENT OF COMMERCE to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are to the days Complete if Known Substitute for form 1449A/PTO 09/757,688 **Application Number INFORMATION DISCLOSURE** January 11, 2001 Filing Date STATEMENT BY APPLICANT Wolfgang HEIL et al. First Named inventor 1615 **Group Art Unit** (use as many sheets as necessary) L.S. Channavajjala **Examiner Name** PLOVIN-2A Sheet 2 2 of **Attorney Docket Number**

		NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						
R		K. Fotherby, et al. "Review: The new low dose oral contraceptives", Journal of Obstetrics and Gynecology, Vol. 14, (1994), pgs. 327-332.						
		L. Speroff, "Review: Evaluation of a new generation of oral contraceptives", The Amer. College of Obstetricians & Gynecologists, Vol. 81, No. 6, (1993), pgs. 1034-1047.						
		J. Urdinola, "Anticonceptivos orales: 30 vs. 20 μg de etinilestradio (EE), pgs. 41-49.						
		J. Endrikat, et al., "A Twelve-Month Comparative Clinical Investigation" Elsevier Science Inc., (1995), pgs. 229-235.						
		D. Mishell, et al., "Postmenopausal hormone replacement with a combination estrogen-progestin regimen for five days per week", "The Journal of Reproductive Medicine, Inc., Vol. 36, No. 5, (1991), pgs. 351-355.						
	S. Sipinen, et al., "Pharmacokinetic studies on low dose estradiol 17β administere orally to postmenopausal women", Acta Obstet Gynecol Scand 59, (1980), pgs. 515-518.							
		J. M. Aitken, et al., "Oestrogen replacement therapy for prevention of osteoporosis after oophorectomy", British Medical Journal, (1973), pgs. 370-375.						
		C. Hassager, et al., "Estorgen/Gestagen therapy changes soft tissue body composition in postmenopausal women", Metabolism, Vol. 38, No. 7, (1989), pgs. 662-665.						
		Ch. Egarter, et al., "Ovarian function during low-dose oral contraceptive use", Elsevier Science Inc., (1995).						
	J. Spona, et al., "Efficacy of low-dose oral contraceptives containing levonorgestrel, gestoden and cyproterone acetate", "Gynecol, obstet, Invest., Vol. 23, (1987), pgs. 184-193.							
\bigvee		The Writing Group for PEPI Trail, "Effects of hormone replacement therapy on endometrial histology in postmenopausal women", Hormone Replacement Therapy, Vol. 275, No. 5, (1996) pgs. 370-375.						
Examin Signatu	LG GL	L. Channavargala Date Considered 4/14/06						

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-latter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. ⁸ Applicant is to place a check mark here if English tanguage Translation is attached.

Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031

TRAFF U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO Complete If Known **Application Number** 09/757,688 **INFORMATION DISCLOSURE** January 11, 2001 Filing Date STATEMENT BY APPLICANT First Named Inventor Wolfgang HEIL et al. 1615 **Group Art Unit** (use as many sheets as necessary) L.S. Channavajjala **Examiner Name PLOVIN-2A** Sheet of **Attorney Docket Number**

		NON PATENT LITERATURE DOCUMENTS	
xaminer Initials *	Cite No.1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2
A	1	Civil Action 05-02308 in U.S. District Court for District of New Jersey, Schering AG Complaint for Patent Infringement of U.S. Patent 6,787,531 against Barr. 4-27-05	
+		Barr Answer and Counter claims in Civil Action 05-02308 6-10-05	
		Schering AG Reply to Barr Counterclaims in Civil Action 05-02308 7-15-05	
			
<u></u>			
	-		
_	·		
Examina Signatur		Chamarajal Date Considered 4/14/66	

<u>U 1</u> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to explicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-latter code (WiPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WiPO Standard ST. 18 If possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Please this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO Complete if Known **Application Number** 09/757,688 **INFORMATION DISCLOSURE** January 11, 2001 Filing Date STATEMENT BY APPLICANT Wolfgang HEIL et al. First Named Inventor 1615 **Group Art Unit** L.S. Channavajjala (use as many sheets as necessary) **Examiner Name**

2 **PLOVIN-2A** Sheet 1 of **Attorney Docket Number** U.S. PATENT DOCUMENTS **U.S. Patent Document** Kind Code² Name of Patentee or Applicant of Cited Document Examiner Initials Date of Publication of Cited Document MM-DD-YYYY Cite No.' (if known) Number 4,616,006 **Pasquale** 10/7/1986

		Foreign Patent Document			D	Date of Publication of	Pages, Columns, Lines, Where Relevant	
Examiner initials	Cite No.1	Office ³	Number ⁴	Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T
		GB	516,444		ABel May 1	1/2/1940		
		DE	702063			1/29/1941		
		-			· ·			<u> </u>
	<u></u>					·		
						•		
Examin					/) Date	-		
Signatu	ire	1.	Chann	aven	Considered	4-14	-21	

EXAMINER: Initial if reference considered, whether or not citation te-th ogniformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16.If possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

CHANGE BE ESTIMANT LOCATION OF 1222 TO TEST OF BEINGHOOF DESTAIN OF CHRONIC ABOUT HEREOF A ACED CAMO COURS DESTAIN. Substitute for form 1449A/PTO Complete if Known 09/757,688 **Application Number INFORMATION DISCLOSURE** Filing Date January 11, 2001 STATEMENT BY APPLICANT First Named Inventor Wolfgang HEIL et al. 1615 **Group Art Unit** (use as many sheets as necessary) L.S. Channavajjala **Examiner Name** PLOVIN-2A 2 of 2 Sheet **Attorney Docket Number**

	-							
	г	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No.*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2					
		G. Levy, "Availability of spironolactone given by mouth, the Lancet, Letters to the Editor, October 6, 1962, pg. 723-724						
		Valle et al., "Farmacologia Integrada – Farmacologia Básia, Vol. I, Livraria Atheneu, Rio de Janeiro, 1998, pgs. 25-27 and 44-45 w/English translation						
		Letter dated 30 August 2005 from the Opponent						
		Translation of Opponent's letter of 30 August 2005						
į		Letter of 2 November 2005 filed in response to Opponent's letter of 30 August 2005.						
		S. Budavari, et al., "The Merck Index", Merck & Co., Inc., Whitehouse Station, NJ (1996)						
. , , , , , , , , , , , , , , , , , , ,								
· ··								
·—								
	<u> </u>							
Examir Signatu		L. Channavande Considered 4-14-06						

EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WiPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WiPO Standard ST. 16 if possible. ⁴ Applicant is to place a check mark here if English language Translation is attached.